DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

FEB 9 2005

Mr. Patrick Noonan
Warner Center Plaza, Suite 840
21800 Oxnard Street
Woodland Hills, California 91367

Dear Mr. Noonan:

This is to inform you that the notification you submitted, dated December 1, 2004, on behalf of your client, Medical Research Institute, pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on December 1, 2004. Your notification concerns the substance called "Creatine" from Creatine Ethyl Ester HCL that you intend to market as a new dietary ingredient.

The notification informs FDA that Medical Research Institute, Inc. intends to market the new dietary ingredient, "Creatine" from Creatine Ethyl Ester HCL in 500 mg, 750 mg and 1000 mg capsules, caplets or tablets. The notification further states that Medical Research Institute will also distribute "Creatine" from Creatine Ethyl Ester HCL as a bulk raw material powder for incorporation into other dietary supplement products. The notification states that the recommended daily dosing of "Creatine" from Creatine Ethyl Ester HCL shall be 500 milligrams to 3 grams per day, consumed in a single or divided daily dose. The conditions of use of "Creatine" from Creatine Ethyl Ester HCL as described in your notification include a statement that "Creatine" from Creatine Ethyl Ester HCL will be recommended for adults only and will not be intended for use by pregnant or lactating women; individuals at risk for renal or hepatic dysfunction; individuals that have been medically prescribed Disulfuram (Antibuse); or individuals with known hypersensitivity to any of the components of Creatine Ethyl Ester HCL. The targeted population for the dietary ingredient "Creatine" from Creatine Ethyl Ester HCL is adults and children over the age of eighteen years of age.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary

supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

It is not readily apparent whether the "Creatine" from Creatine Ethyl Ester HCL that is the subject of your notification is a dietary ingredient within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;
(B) a mineral;
(C) an herb or other botanical:
(D) an amino acid;
(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

Based on the information in your submission, it is unclear that "Creatine" from Creatine Ethyl Ester HCL is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1). Therefore, FDA cannot determine, at this time, whether your product is a new dietary ingredient that may lawfully be marketed as a component of a dietary supplement.

FDA intends to complete its evaluation shortly and send you a response to your notification explaining FDA's decision about whether your product is a dietary supplement within the meaning of 21 U.S.C. 321(ff)(1).

This letter is to alert you within the 75-day notification period that FDA has concerns about whether your product can lawfully be marketed as a dietary supplement. Please note that failure to respond to a notification within the 75-day timeframe does not constitute a finding by the agency that the ingredient or a product that contains the ingredient is safe or is not adulterated under 21 U.S.C. 342. 21 C.F.R. 190.6(f).

Your notification will be kept confidential for 90 days after the filing date of December 1, 2005. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Dr. Linda Pellicore at (301) 436-2375.

Sincerely yours,

for Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition